

Notice of Allowability

Application No.

10/791,980

Examiner

Sheridan L. Swope

Applicant(s)

WOOD ET AL.

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to telephonic election of November 17, 2005.
2. ☒ The allowed claim(s) is/are 1 and 7.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 0304
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

Claims 1-10 are pending.

During a telephone conversation with Gwilym Attwell on November 7, 2005 a election was made, without traverse, to prosecute Invention I, Claims 1-7, set forth by the Election/Restriction requirement of October 24, 2005. Claims 8-10 are withdrawn from further consideration, pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Claims 1-7 are herein examined.

Information Disclosure Statement

It is noted that Information Disclosure Statement submitted on March 3, 2004 comprises copies of the 892 forms from parent Application 09/862,631. The use of an 892 form from a prior application as an Information Disclosure Statement is improper (MPEP 6.49.08). In the interest of compact prosecution and public service, the Examiner has listed all references on the prior 892 forms from parent Application 09/862,631 on the 892 form for the instant application.

Examiner's note regarding equivalence of references:

–Falduto et al 1998 New isolated human matrix metalloprotease gene. Derwent Acc# AAV08170 from WO9840475 alignment with SEQ ID NO: 6– from 09/862,631 is equivalent to –Issued_Patents_NA Database US 6,399,371 17-MAY-2002 Falduto et al. SEQ ID NO: 10. Alignment with SEQ ID NO: 6– cited herein.

–Falduto et al 2002 (filing date 03-1997) Human matrix metalloprotease gene, proteins encoded therefrom and methods of using same. SEQ ID NO: 1 of US6399371 alignment with SEQ ID NO: 6– from 09/862,631 is equivalent to – Issued_Patents_NA Database US 6,399,371 17-MAY-2002 Falduto et al. SEQ ID NO: 1. Alignment with SEQ ID NO: 3.– cited herein.

– Lohi et al, 2001 EMBL Acc# AF219624. Alignment with SID 6.– from 09/862,631 is equivalent to – UniProt Database Accession No. MM28_HUMAN 10-OCT-2003 from Lohi et al., Epilysin, a novel human matrix metalloproteinase (MMP-28) expressed in testis and keratinocytes.... J Biol Chem. 2001 Mar 30;276(13):10134-44. Alignment with SEQ ID NO: 6.– cited herein.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Title

Replace the title with: ~~–A matrix metalloproteinase polypeptide–~~.

Specification

On page 1, line 2, replace ~~–2001, which–~~ with: ~~–2001, which issued as US 6,734,005 on May 11, 2004 and, which–~~.

Claims

Cancel Claims 2-6 and 8-10.

Replace Claims 1 and 7 with:

1. An isolated polypeptide comprising a sequence with at least 99% sequence homology to SEQ ID NO: 6, said polypeptide having matrix metalloproteinase (MMP) activity, wherein sequence homology is determined using the Gap program with default settings.
7. A composition comprising the polypeptide of claim 1 and an acceptable carrier or diluent.

Authorization for this examiner's amendment was given in a telephone interview with Gwilym Attwell on November 16, 2005.

Allowable Subject Matter

Claims 1 and 7 are allowed.

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The following is an examiner's statement of reasons for allowance:

All elected claims, Claims 1 and 7, are limited to isolated polypeptides having at least 99% sequence homology to SEQ ID NO: 6, said polypeptides having matrix metalloproteinase activity, wherein sequence homology is determined using the Gap program with default settings. Support for Applicants' limitation of "wherein sequence homology is determined using the Gap program with default settings" can be found in the specification (pg 13, parag 5).

The recited invention is free of the art. The polypeptide of SEQ ID NO: 6 is encoded by the nucleic acid sequence set forth by SEQ ID NO: 3 herein. It is noted that the polynucleotide of Falduto et al, 2002 (filing date September 7, 1999) has 98% identity with SEQ ID NO: 3 (see enclosed alignment). However, because the polynucleotide of Falduto et al includes two shifts in reading frame, compared to SEQ ID NO: 3, the polynucleotide of Falduto et al encodes a protein that has only 88% identity with SEQ ID NO: 6 (see enclosed alignment). Therefore, Falduto et al, 2002 does not anticipate the instant claims.

The utility of the recited polypeptides, as having matrix metalloprotease, is credible based on homology to a protein of known function. The polypeptide of SEQ ID NO: 6 has 87% identity with the epilysin metalloprotease of Lohi et al, 2001 and, furthermore, comprises the conserved catalytic motif HEIGHTLGLTHS at residues 241-252 (see enclosed alignment). Lohi et al teach that their metalloprotease cleaves casein (Fig 9). Based on homology with the metalloprotease of Lohi et al, a person of ordinary skill in the art would believe that, more likely than not, the polypeptide of SEQ ID NO: 6 also cleaves casein. Enzymes that cleave casein have commercial use for the preparation of caseinophosphopeptides, a feed additive that aids in the

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adsorption of calcium (McDonagh et al, 1998). Thus, the polypeptide of SEQ ID NO: 6 has a specific, substantial, and credible utility.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.

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SHERIDAN SWOPE, Ph.D.
PATENT EXAMINER